

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of Health
and Human Services.

Defendant.

Case No. 3:20-cv-00687

(Hon. Martin Carlson)

Electronically Filed

**PLAINTIFF'S COMBINED OPPOSITION TO DEFENDANT'S CROSS-
MOTION FOR SUMMARY JUDGMENT AND REPLY TO DEFENDANT'S
OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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I. PRELIMINARY STATEMENT

Plaintiff Maureen Piekanski respectfully files this combined opposition to the Defendant Alex Azar, in his official capacity as Secretary of Health and Human Services’ (the “Secretary”), cross motion for summary judgment and reply to his opposition to her motion for summary judgment. The Secretary’s motion does not rebut the presumption of the application of collateral estoppel or show that the elements of collateral estoppel are not present in this case. Further, contrary to FED.R.CIV.P. 56(a) (“*part* of each claim or defense”), the Secretary contends that, by moving for summary judgment based on collateral estoppel, Mrs. Piekanski has abandoned all other arguments that go to the actual merits. There is nothing to that charge. Mrs. Piekanski’s motion for summary judgment should be granted, the Secretary’s motion denied, and this case remanded to the Secretary with instructions to provide for coverage.

II. SECRETARY’S RESPONSE TO PLAINTIFF’S SUMMARY OF UNDISPUTED MATERIAL FACTS

The Secretary does not specifically dispute Mrs. Piekanski’s material facts. *See* Dkt. #50-2. The Secretary did respond in a variety of ways, short of denying Mrs. Piekanski’s facts. At most, the Secretary added information to the Plaintiff’s summary of each prior ALJ decisions’ issues and holdings, but did not controvert Mrs. Piekanski’s factual assertions. *See e.g.*, Dkt. #50-2 at ¶¶ 10-13, 19, 21. The Secretary attempted to avoid either admitting or disputing several of Mrs.

Piekanski's facts (Dkt. #50-2 at ¶¶ 4, 24-49, 52) by asserting a legal conclusion regarding the "admissibility" of evidence. Mrs. Piekanski cited to the administrative record for each fact, so an assertion regarding the admissibility of decisions already part of the administrative record is disingenuous and not a denial of the facts. Per LR 56.1, any fact not controverted is deemed admitted. As a result, the Secretary has admitted Mrs. Piekanski's facts.

III. DISCUSSION

Nearly all of the Secretary's brief addresses issues other than the elements of collateral estoppel. Accordingly, in the interest of clarity, Mrs. Piekanski will primarily address the elements of collateral estoppel before turning to the Secretary's other arguments.

A. The Record

The Secretary alludes to evidence outside of the administrative record and argues that a review of the case should be limited to the administrative record. *See* Dkt. #50 at 32-34. The Court may properly consider these materials as set forth in Mrs. Piekanski's motion. *See* Dkt. # 28-15 at 13-14. The nature of collateral estoppel is that a final decision giving rise to collateral estoppel can occur after the non-final decision being estopped. Thus, at least partly because of the manner in which collateral estoppel may arise, judicial notice of other proceedings/decisions giving rise to collateral estoppel is common.

As established in Mrs. Piekanski's moving papers, in similar circumstances, the Seventh Circuit took judicial notice of other proceedings to vacate an agency determination. *See* Dkt. # 28-15 at 13-14. In *Opoka v. INS*, 94 F.3d 392 (7th Cir. 1996), the Seventh Circuit took judicial notice of later proceedings to vacate and remand a Board of Immigration Appeals decision, the review of which was limited to the record before it. The Seventh Circuit held that it would be "derelict" in its duty if it did not take notice of the later proceeding. *Id.* at 394-95. *See also Golden Hill Paugussett Tribe of Indians v. Rell*, 463 F.Supp.2d 192, 197 (D. Conn. 2006) (court took judicial notice of a Board of Indian Appeals decision that issued after the immediate case was filed, which precluded a group from claiming tribal status in its action seeking to nullify conveyances of land).

Pursuant to 42 U.S.C. § 405(g), this Court may base its decision "upon the pleadings and transcript of the record." Thus, this Court can properly consider the materials cited by Mrs. Piekanski as part of the "pleadings" in this case or simply as facts that have independent legal significance.

B. Collateral Estoppel May Be Based on a Later-Issued Decision

As set forth in Mrs. Piekanski's moving papers, where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other (even first filed) litigation that is still ongoing. Dkt. # 28-15 at 3, 20-21. *See also Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484

(7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]”); *Rashid v. Hazleton*, No. 93-1135, 1996 WL 114809, at *4 (E.D. Pa. March 14, 1996) (“the collateral estoppel effect of a judgment is determined by the timing of the judgment, not by the timing of the complaint which led to the judgment”).

In other words, a later-filed case that reaches finality first may have preclusive effect on earlier-filed, but still on-going litigation. For example, in *Chicago, R.I. & P. Ry. Co., v. Elder*, 270 U.S. 611 (1926), the Supreme Court held:

Nor is it material that the action proceeding, in which the judgment, set up as an estoppel, is rendered, was brought after the commencement of the action or proceeding in which it is pleaded. ... Whenever a judgment is rendered in one of the courts and pleaded in the other the effect of that judgment is to be determined by the application of the principles of res judicata by the court in which the action is still pending in the orderly exercise of its jurisdiction, as it would determine any other question of fact or law arising in the progress of the case.

Id. at 615-16.¹

¹ “Res judicata” is a legal doctrine incorporating the concepts of “claim preclusion” (formerly known as “merger” and “bar”) and “issue preclusion” (formerly known as “collateral estoppel”). The confusing use of these terms has led to modern efforts to limit “res judicata” to mean “claim preclusion” and to use the term “issue preclusion” instead of “collateral estoppel.” See THE RESTATEMENT (SECOND) OF JUDGMENTS (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984).

Thus, the Secretary's contention that collateral estoppel cannot apply because the final ALJ Glaze, Soulikias, and Myles decisions issued after the non-final unfavorable ALJ Glaze decision is without basis.

C. The Standard of Review

The Secretary's statements regarding the standard of review are incomplete. Dkt. # 50 at 11. As set forth in 42 U.S.C. § 405(g), only the factual conclusions of the Secretary are subject to the "substantial evidence" standard. In all other respects, the Secretary's decision is reviewed using any standard under the Administrative Procedure Act/federal law. *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) (applying arbitrary and capricious standard). Likewise, as detailed in Mrs. Piekanski's motion (Dkt. # 28-15 at 13-14), this Court may take judicial notice of matters related to collateral estoppel, such as the favorable decision of Judge Myles. Under 42 U.S.C. § 405(g), the Court's review may be based on the pleadings and "the transcript of the record." The "transcript of the record" includes all the proceedings before the Department, including those before the Departmental Appeals Board ("DAB"). The decisions of ALJs Gulin, Glaze, and Soulikias are part of the record in this case. *See* CAR 16-25, 41-50, 26-40. Thus, the Court may properly consider each of the ALJs' decisions as part of the "record", in addition to the Court's power to take judicial notice of the decisions. Regardless, the Secretary conceded that Judge Glaze had a copy of Judge Gulin's favorable determination

before him in the instant case. *See* Dkt. # 50-2 (Def.'s Opposition to Pl.'s Statement of Undisputed Material Facts) at ¶ 22.

The Secretary further alleges that the Court should only consider the facts known to the agency at the time the decision was made. Dkt. # 50 at 32-34. Clearly, that is a contention without basis. First, at the time the Council made the decision to let ALJ Glaze's unfavorable decision stand (by failing/refusing to issue its own decision), the Council knew of the fact of three prior favorable decisions. *See* CAR 16-25, 41-50, 26-40. Second, as advanced by the Secretary, a final decision in one case could not have preclusive effect on the non-decision in another case. That is contrary to, *e.g.*, the Supreme Court's decisions in *Kline* and *Elder* holding that where parallel/concurrent litigation is present, whichever case reaches finality first may have preclusive effect on the other. Dkt. # 28-15 at 3. Because of this standard, it is evident that cases will arise where after a non-final decision is made, a final decision arises that may be controlling. Thus, the Court's review is not limited to the facts known to either ALJ Glaze or the Council.

D. Collateral Estoppel Applies to Medicare Cases²

As set forth in *Astoria Federal Savings and Loan v. Solomino*, 501 U.S. 104, 108 (1991), there is a presumption that common law principles (including collateral estoppel) apply to agencies when they act in a “judicial capacity.” *Id.* at 108 (“[W]here a common-law principle is well established, as are the rules of preclusion, the court may take it as a given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident.”) (internal citations and quotations omitted).

As explained by the Supreme Court in *U.S. v. Texas*, “*statutes* which invade the common law are to be read with a presumption favoring the retention of long-established and familiar principles, except where a statutory purpose to the contrary is evident.” 507 U.S. at 534 (internal citations and quotations omitted, emphasis added). “In order to abrogate a common-law principle, the *statute* must ‘speak directly’ to the question addressed by the common law.” *Id.* (internal citations and quotations omitted, emphasis added). Moreover, if the text of the statute is “compatible with preexisting practice”, then the presumption is not overcome. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994). The party asserting that

² The Secretary cited to a non-final decision in the Eastern District of Wisconsin regarding the applicability of collateral estoppel in analogous circumstances. *Christenson v. Azar*, Case No. 20-cv-00194 (Jul. 6, 2020). Importantly, the court is currently considering the plaintiff’s Motion for Reconsideration in that case, based on manifest errors of law. *See* attached Exhibit A.

a statute abrogates common law bears the burden of overcoming the presumption. *See, e.g., Green v. Block Laundry Machine Co.*, 490 U.S. 504, 521 (1989) (“A party contending that legislative action changed settled law has the burden of showing that the legislature intended such a change.”).

In the present case, the Secretary has not carried his burden to rebut the presumption of the application of collateral estoppel to Medicare cases. As explained by the Supreme Court in *Astoria, U.S. v. Texas*, and *Green* the focus with regard to the presumption is on congressional/legislative intent, *not* the intent of the Secretary. *Astoria*, 501 U.S. at 109-10 (“absent clearly expressed congressional intent to the contrary”; “consistent with Congress’ intent”); *U.S. v. Texas*, 507 U.S. at 535 (“an expression of legislative intent to supplant”); *Green*, 490 U.S. at 521 (“legislature intended such a change”).

Indeed, even the Secretary’s citation to *Duvall v. Atty. Gen. of U.S.*, 426 F.3d 382, 387-388 (3d Cir. 2006), in which the Third Circuit applied collateral estoppel in an administrative case, makes Mrs. Piekanski’s point in this regard. Dkt. # 50 at 12 (preclusion should not apply if it “would frustrate congressional intent”; *Duvall* at 389 (“opinions that have held that collateral estoppel does not apply in a particular administrative context have been premised on language in the governing statute expressing a contrary intent, language which does not appear in the INA.”)).

The only statute discussed by the Secretary in this regard refers to Council consideration of ALJ appeals “*de novo*.” Dkt. # 50 at 16 (citing 42 U.S.C. § 1395ff(d)(2)(B)). *De novo* review does not “speak directly” to the issue of collateral estoppel or evidence a statutory purpose to the contrary. Stated differently, *de novo* review is “compatible with the preexisting practice” of collateral estoppel. *See BFP*, 511 U.S. at 543. Thus, the presumption has not been overcome.

De novo review merely means that the reviewing court conducts its review “independent, with no deference given to the trial court’s conclusion.” *See e.g., In re: Deitz*, 760 F.3d 1028, 1043 (9th Cir. 2014). Thus, the reviewing court decides matters in the same stead as the court/tribunal appealed from without any deference to the conclusions reached by the court/tribunal being reviewed.

Of course, such *de novo* review does not mean the reviewing court can proceed without regard to any legal principles/doctrines. Courts routinely apply collateral estoppel in matters subject to *de novo* consideration/review. Indeed, orders granting summary judgment based on collateral estoppel are subject to *de novo* appellate review, as is the application of collateral estoppel itself. *See, e.g., Prusky v. Reliastar Life Ins. Co.*, 532 F.3d 252, 265 (3d Cir. 2008) (applying *de novo* review to both issues); *S.E.C. v. Monarch Funding Corp.*, 192 F.3d 295, 303 (2d Cir. 1999) (“We review a district court’s grant of summary judgment based on the doctrine of collateral estoppel *de novo*”); *Miccosukee Tribe of Indians v. U.S. Army*

Corps of Engineers, 619 F.3d 1289, 1296 (11th Cir. 2010) (“We review the district court’s invocation of collateral estoppel *de novo*.”); *Mike Smith Pontiac, GMC, Inc., v. Mercedes-Benz of North America, Inc.*, 32 F.3d 528, 522 (11th Cir. 1994) (“We review *de novo* a grant of summary judgment on grounds of collateral estoppel”). Thus, the Secretary did not carry his burden to rebut the presumption of collateral estoppel.

Other than the statute providing for *de novo* review by the Council, the Secretary did not cite to any other statute allegedly evidencing Congress’ intent to abrogate the common law of collateral estoppel in Medicare cases. Instead, the Secretary’s papers are filled with references to the Secretary’s regulations. Dkt. # 50 at 13-15. Of course, regulations are not statutes - so they have no relevance in this regard. As explained by the Supreme Court, the focus is on congressional/legislative intent, not the intent of the Secretary. *Astoria*, 501 U.S. at 109-10 (“absent clearly expressed congressional intent to the contrary”; “consistent with Congress’ intent”); *U.S. v. Texas*, 507 U.S. at 535 (“an expression of legislative intent to supplant”); *Green*, 490 U.S. at 521 (“legislature intended such a change”). Thus, the Secretary cannot rely on regulations to reflect congressional intent. Accordingly, the presumption of the common law principle of collateral estoppel has not been overcome.

Another court has supported the use of estoppel against the Secretary in analogous circumstances, highlighting a lack of caselaw supporting the Secretary's position that he cannot be bound by prior decisions for subsequent claims involving the same plaintiff for the same device. In considering a device supplier's challenge to a Medicare contractor's recoding decision (following numerous final favorable ALJ decisions overruling overpayment determinations on the basis of the appropriate use of an existing code), the District of Nebraska found that the Secretary did not cite to any caselaw to indicate "that the Secretary is not bound by the agency's earlier determinations vis-à-vis the same claimant, the same device, and an unchanged procedure code." *DeWall Enterprises, Inc., v. Thompson*, 206 F.Supp.2d 992, 1001 (D. Neb. 2002). In granting the supplier's preliminary injunction, the *DeWall* court noted that "the Secretary is simply not free to inconsistently interpret its own rules and regulations and to continue to run a claimant through a never-ending gauntlet in pursuit of his rights." *Id.* Mrs. Piekanski seeks to avoid such inconsistency.

The Secretary did not rebut the presumption of the application of collateral estoppel, while Mrs. Piekanski has shown that each of the elements are present.

1. The Issue Sought to Be Precluded is Identical to That Raised in Previous Proceedings

As noted in Mrs. Piekanski's moving papers, Mrs. Piekanski set forth a series of undisputed facts in compliance with LR 56.1. Several of those facts relate to what

issues were the subject of the decisions of ALJs Gulin, Glaze, Soulikias, and Myles. *See* Dkt. # 28-16, Pl.’s Statement of Undisputed Facts (“SUMF”) ¶¶ 10, 12; 28; 37; 46. As set forth, those facts state identical issues in each decision, and identical to the issue presented before Judge Glaze in the instant case. *Id.* at ¶19.

The Secretary has not shown that the issues at stake were not identical, despite his attempts in his Statement of Undisputed Material Facts (Dkt. # 50-2 at ¶¶ 10-13) to argue that different dates of service amount to different issues for the same device, for the same beneficiary, for the same disease. It is well settled that the test for determining whether facts/issues are the same between two decisions for collateral estoppel purposes is “materiality.” That is, facts/issues are the same unless they are materially different with respect to the conclusions reached (i.e., “changed circumstances”). *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) (“changes in facts essential to a judgment will render collateral estoppel inapplicable”); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) (“identical in all material aspects”).

In the present case, the Secretary has not shown that there is a material difference between TTFT coverage for Mrs. Piekanski between, e.g., November 2017 (when ALJ Gulin found it was covered); December 2017 (when ALJ Glaze found it was not covered); and June 2018 (when ALJ Glaze found it was covered). There is no evidence that TTFT got any less safe and effective, less life-extending,

less “medically reasonable and necessary” for Mrs. Piekanski, or less of a Medicare covered benefit (or more of one) in the passage of a few months. Of course, ALJs Gulin, Glaze, Soulikias, and Myles could only decide the claims for coverage before them. Thus, the fact that each decision describes the months that it relates to says nothing about whether the same issues were at stake. As shown, they were.

The identical issues of whether TTFT was medically reasonable and necessary and a Medicare covered benefit for Mrs. Piekanski were at stake in each case.

2. The Issue was Actually Litigated in the Prior Proceedings

The Secretary asserts that the same issue was not actually litigated in the prior proceeding for the same reason the Secretary asserts identical issues were not at stake. – i.e., each decision concerns different months of coverage and each decision resulted from a specific submission of evidence. Mrs. Piekanski established that the issues of “medically reasonable and necessary” and “Medicare covered benefit” were actually litigated and decided before ALJs Gulin, Glaze, Soulikias, and Myles. *See* Dkt. # 28-16, SUMF ¶¶10-13; 28-30; 37-39; 46-48. Regarding the Secretary’s assertion in his SUMF that the issues presented in the decisions of Judges Glaze, Soulikias, and Myles should be excluded as they were not before Judge Glaze in the instant case (Dkt. # 50-2 at ¶¶ 24-49), Mrs. Piekanski notes above that the decisions of Judges Glaze and Soulikias are part of the administrative record and therefore properly considered here; and it would similarly be proper to either consider Judge

Myles' decision as part of the pleadings of the case or to take judicial notice of the same. *See* §§ I.A., I.C. above. The Secretary did not otherwise dispute the substance of Mrs. Piekanski's factual assertions in this regard.

Notably, the Secretary's decision to not participate in any of the cases does not impact whether the issues were "actually litigated." Specifically, in contrast to a default judgment, the Secretary had the opportunity to appear and Plaintiff was put to his burden of proof in each of the prior cases deciding coverage. In such a situation, a matter is "actually litigated." *See Restatement (Second) of Judgments* § 27 cmt. d (1982) ("When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination and is determined, the issue is actually litigated."); *Matter of Garner*, 56 F.3d 677, 680 (5th Cir. 1996) (defendant who answered Complaint but did not otherwise appear, bound by collateral estoppel because plaintiff put to burden of proof). Thus, in the present case, the identical issues were "litigated on the merits"/"actually litigated" because Plaintiff was put to her burden of proof and the Secretary's decision not to appear at the hearings only means that the Secretary relied on that burden of proof as defense of the claim.

3. The Issue was Determined by Valid and Final Judgments

The Secretary does not contest or address in his cross motion that the issues were decided by valid and final judgments. Therefore, the Secretary concedes that this element of collateral estoppel is fulfilled.

4. The Determination was Essential to the Prior Judgment

Again, the Secretary's cross motion for summary judgment does not address this element of collateral estoppel. The Secretary does not contest in his brief that the determinations regarding reasonableness and medical necessity were essential to the prior judgments. As summarized in Mrs. Piekanski's moving papers, essential to the prior, final judgments was a determination that TTFT was "medically reasonable and necessary." Because something is a Medicare covered benefit only if it is "medically reasonable and necessary", that determination was critical to each judge's decision. Each judge explicitly decided the sub-issue of medical reasonableness and necessity. Dkt. # 28-16 at SUMF ¶¶ 13, 30, 39, 48.

E. The Secretary's Other Comments

As noted above, there is a presumption that collateral estoppel applies when an agency is acting in a "judicial capacity." *Astoria*, 501 U.S. at 108. The Secretary did not rebut that presumption. However, Mrs. Piekanski will address the additional extraneous arguments proffered by the Secretary.

1. The Secretary's Comments Regarding LCDs

On pages 3-10 of the Secretary's Cross Motion for Summary Judgment, the Secretary sets forth various background information. A response to most of it is unnecessary and the entire section seems irrelevant to the issue of collateral estoppel. That said, a few comments are either erroneous or incomplete.

It is true that local coverage determinations (LCDs) are supposed to be developed by considering medical literature, etc. and be reviewed to ensure that they do not become outdated. Dkt. # 50 at 6-7. However, the Secretary did not mention that this did not happen in the case of TTFT. That is, the LCD that became effective on October 1, 2015 did not consider the suspension of the clinical trial in 2014 on the grounds that withholding TTFT from the control group would have been unethical. Likewise, the LCD was not reviewed after its issuance and did not consider the large number of scientific studies showing the effectiveness of TTFT, additional FDA approval in October 2015, the fact that TTFT had become the standard of care for GBM no later than 2018, as well as clinical trials and seminal papers concerning the same. Because of this complete failure of process, in May 2019, ALJ Scott Anderson determined that the 2015 LCD concerning TTFT was not supported by substantial evidence. *See* Exhibit B attached hereto. ALJ Anderson's decision was the result of an LCD challenge by a Medicare beneficiary (i.e., the "Aggrieved Party") contending that the LCD was not supported by substantial evidence. Thereafter, the Contractor submitted a revised LCD (that is also being challenged) that only applies to dates of service after September 1, 2019.

2. It is Not Unfair to Apply Collateral Estoppel Offensively

The Secretary's comments with regard to this issue are a series of strawmen. Dkt. # 50 at 27-31. As previously noted, Mrs. Piekanski was represented and the

Secretary therefore had the full panoply of rights of any litigant. Dkt. # 28-15 at 8-9. Thus, the Secretary had all the rights of any litigant, including appeal. See 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of what the Secretary chose to do before the ALJ or at the ALJ level, the Secretary could have appealed on so-called “own motion review.” See 42 C.F.R. § 405.1110. The Secretary’s arguments fail on both law and policy grounds.

First, the Secretary argues generally that application of collateral estoppel against the government offensively is inappropriate. Dkt. # 50 27-29. The Supreme Court has held otherwise. In *U.S. v. Mendoza*, 464 U.S. 154 (1984), the Supreme Court noted, e.g., that the United States is a party to ~36% of the district court cases filed in a given year. In consideration of this fact, *inter alia*, the Supreme Court held that non-mutual collateral estoppel would not apply to the United States. At the same time, however, the Supreme Court affirmed the long-standing rule that mutual (even offensive) collateral estoppel applied to the United States. *Id.* at 159-164. Mrs. Piekanski therefore properly asserts mutual collateral estoppel against the Secretary.

Second, the Secretary offers a number of comments regarding the determination of “future claims” by Mrs. Piekanski. Dkt. # 50 at 30-31. These comments misapprehend the entire basis of this case and the relief sought. Mrs. Piekanski seeks only relief for the denied claims that are at issue in this case and no

prospective relief of any kind is sought. That is, Mrs. Piekanski seeks only a determination regarding the claims that are the subject of ALJ Glaze’s unfavorable decision and seeks no relief with respect to any “future claims” Mrs. Piekanski may have. Whether collateral estoppel will apply to any future claims of Mrs. Piekanski will depend on the facts and circumstances at the time those claims are submitted. Accordingly, the Secretary’s comments in this regard are simply irrelevant.

Likewise irrelevant are the Secretary’s comments regarding *Porzecanski, v. Azar*, 943 F.3d 472 (D.C. Cir. 2019) (Dkt. # 50 at 30-31). In *Porzecanski*, the plaintiff sought an injunction mandating coverage of any “future claims” the plaintiff might submit. *Id.* at 475 (“prospective equitable relief”). By contrast, Mrs. Piekanski seeks only retrospective relief.³

Further, the Secretary’s reading of the *Porzecanski* case is erroneous. Dkt. # 50 at 30-31. In *Porzecanski*, the plaintiff both appealed the denial of a Medicare claim and sought declaratory and injunctive relief regarding any “future claims” he might submit. While reversing the denial of coverage for the claim at issue, the district court concluded that it could not issue declaratory and injunctive relief as to possible “future claims.” Only the denial of declaratory and injunctive relief as to “future claims” was the subject of appeal and the district court’s decision as to the

³ As set forth in the Complaint, a case like this technically seeks “injunctive relief” not “damages” (i.e., an injunction requiring the Secretary to provide coverage for the claims at issue). See *Bowen v. Massachusetts*, 487 U.S. 879, 893-901 (1988).

claim actually denied was not at issue. *See Porzecanski*, 943 F.3d at 477-78. *Porzecanski* said nothing about collateral estoppel or preclusion with respect to the claim actually appealed to (and reversed by) the district court and only concerned the request for prospective relief.

3. The Secretary's Comments Regarding Appeal Volumes

In an attempt to further his argument that applying collateral estoppel would be unfair, the Secretary asserts that it “would not be practicable” for the Secretary to participate in ALJ appeals. Dkt. # 50 at 29. In support of that claim, the Secretary asserts it impracticable “for the Secretary to defend himself in thousands of ALJ appeals filed each year” (citing, among other things, a January 17, 2017 Federal Register publication). The Secretary’s factual claims are unsupported by any record evidence and his argument is unavailing.

The Secretary’s argument fails on policy grounds. Specifically, as noted above, the Supreme Court considered in *Mendoza* the burden on the government in defending itself in approximately 36% of the district court cases filed in a given year. The notion that collateral estoppel would be unfair to apply in the mutual, offensive context against the United States, given this approximate case volume, was rejected. Rather, the Supreme Court affirmed the long-standing rule that mutual offensive collateral estoppel could be applied against the United States. *Mendoza* at 159-164.

To the extent that the Secretary alleges that it would be inefficient for the Secretary to litigate these cases, there is no support for that claim. Indeed, not applying collateral estoppel would be inefficient. For example, here, Mrs. Piekanski retained counsel and fully litigated the issue of TTFT coverage. Thereafter, an ALJ held a hearing and issued a written decision on the matter. If collateral estoppel is applied, that should largely be the end of the matter going forward (i.e., as long as there are not changed circumstances). By contrast, the Secretary proposes an indefinite investment of resources (by both Mrs. Piekanski and the Secretary himself through the ALJ) to litigate the identical issues. Avoiding that is the very purpose of collateral estoppel.

Moreover, on evidentiary grounds, it would be improper to allow the Secretary to rely on vague, aggregate data in his Cross-Motion that Mrs. Piekanski cannot oppose. Specifically, the Secretary offers non-record evidence of pending appeal data before the Office of Medicare Hearings and Appeals (OMHA). Dkt. # 50 at 29. No record evidence supports the data relied upon by the Secretary to argue that applying collateral estoppel against the Secretary would be unfair. *Id.*

Mrs. Piekanski cannot oppose the Cross-Motion without the only relevant facts in this regard, the number of ALJ appeals initiated by beneficiaries who are represented by counsel in FYs 2018 and 2019. The Secretary has not offered this data in his briefing. To date, Mrs. Piekanski has been prevented from obtaining this

data from the Secretary, despite her efforts to depose the Secretary regarding the same. Dkt. #55. Therefore, Mrs. Piekanski has filed a contemporaneous motion to either deny or stay the Secretary's Cross-Motion pursuant to Fed.R.Civ.P. 56(d). Alternatively, in the same motion, Mrs. Piekanski proposes striking the relevant portions of the Secretary's brief pertaining to appeal volumes justifying his position that applying collateral estoppel would be unfair.

The Secretary has refused to provide any information on the number of beneficiary appeals where the beneficiary is represented and, therefore, there is no record evidence to support the Secretary's claim. The Secretary should not be able to unilaterally offer alleged, non-record facts in support of his argument.

In any event, the data offered by the Secretary is insufficient to support his argument that the application of collateral estoppel would be unfair given the Supreme Court's finding in *Mendoza*. The Secretary's fairness argument regarding appeal volumes fails on both policy and evidentiary grounds.

4. There are No Changed Circumstances

The Secretary seeks to prevent the application of collateral estoppel by stating that both Mrs. Piekanski's particular circumstances and legal authority have changed over the course of her disease. Dkt. # 50 at 26-27. However, the inconsistency of the decisions themselves highlight why collateral estoppel should apply in this case.

First, the issue of her diagnosis itself is precluded. Judge Gulin noted that Mrs. Piekanski was considered newly diagnosed with GBM in his November 7, 2018 decision (dates of service September – November 2017). Dkt. #28-16, Pl.’s SUMF ¶ 52. That decision became final when the Secretary elected not to appeal it to the Medicare Appeals Council. *Id.* at ¶14. Judge Glaze, in the instant case, thereafter designated Mrs. Piekanski’s disease as recurrent on January 18, 2019 (dates of service December 2017 – February 2018). *Id.* at ¶ 52.

Remarkably, in covering subsequent claims for Mrs. Piekanski in his September 13, 2019 favorable decision (dates of service June – August 2018), Judge Glaze reversed his prior designation and considered Mrs. Piekanski to be newly diagnosed. *Id.* at ¶ 52. The other subsequent favorable decisions designated Mrs. Piekanski as recurrent again. *Id.* To illustrate the impossibility of a GBM patient being “newly diagnosed” after the GBM already progressed, it is useful to think of an egg. Once cracked, an egg can never be considered an unbroken whole again. It is the same with recurrent patients; once their disease progresses beyond its original margins by a certain percentage and they are deemed to have recurrent disease, they can never be considered newly diagnosed again.

The fact that Mrs. Piekanski may have recurred is irrelevant because subsequent decisions (including one from Judge Glaze again who impossibly recharacterized her disease as newly diagnosed) have affirmed that Mrs. Piekanski’s

TTFT is reasonable and necessary for her and a Medicare covered benefit (whether she was considered to be newly diagnosed or recurrent).

The inconsistency associated with the characterization of Mrs. Piekanski's diagnosis illustrates the very purpose of collateral estoppel. As noted above, a patient cannot become newly diagnosed with the disease after it has already recurred/progressed. Judge Glaze nonetheless described Mrs. Piekanski as newly diagnosed with GBM subsequent to his decision at issue in this case, in which he described Mrs. Piekanski as recurrent. Dkt. # 28-16, ¶52. Avoiding nonsensical, inconsistent results like this is one purpose of collateral estoppel. *Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

It is unclear what change in law during the relevant dates of service the Secretary contends would prevent the application of collateral estoppel. The Secretary alludes to an LCD reconsideration process that differentiated coverage based newly diagnosed and recurrent disease. Dkt. # 50 at 27. However, as noted above, the LCD did not go into effect until September 1, 2019 for dates of service on after September 1, 2019, well after the dates of service in the instant case. The non-binding LCD in existence during the dates of service at issue provided for noncoverage for TTFT generally, whether a beneficiary had newly diagnosed or recurrent disease. There were no changed circumstances, factual or legal, that would prevent the application of collateral estoppel. In fact, application of collateral

estoppel will prevent the inconsistency in decision-making illustrated in this case for the same beneficiary, for the same device, for the same illness.

5. There is No Statutory Purpose to the Contrary

The Secretary asserts that collateral estoppel cannot apply when there is a statutory purpose to the contrary. Dkt. # 50 at 12-16. As noted above in Ms. Piekanski's discussion of the presumption of collateral estoppel, the only statute discussed by the Secretary in this regard refers to Council consideration of ALJ appeals "*de novo*." *Id.* at 16 (citing 42 U.S.C. § 1395ff(d)(2)(B)). Other than the *de novo* review provision, the Secretary merely cites to his own regulations as demonstrating an alleged contrary purpose. *Id.* at 12-15. Regulations are not statutes - so they have no relevance in this regard. To the extent that the Secretary relies on regulations to overcome the presumption of the application of collateral estoppel (Dkt. # 50 at 12-15), that also contradicts the instructions of the Supreme Court in *Astoria*, *U.S. v. Texas*, and *Green*.

The Secretary's citation to *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012) (Dkt. # 50 at 13, 15) is inapposite as that case involved only an "arbitrary and capricious" review across multiple cases (and apparently different plaintiffs) and not collateral estoppel. *See e.g., Almy*, 679 at 310 (discussing how the Medicare Appeals Council is not bound by "decisions of lower reviewing bodies addressing different disputes between different parties"). In contrast, here, Mrs. Piekanski seeks to

collaterally estop the Secretary (the same party she prevailed against numerous times in final ALJ decisions) from denying claims for Mrs. Piekanski (the same party who prevailed numerous times in final ALJ decisions) for the same device regarding the same issues.

6. The Secretary's Comments on "Precedential" Decisions and Collateral Estoppel Are Misguided

Respectfully, it is difficult to follow the Secretary's comments regarding "precedential" decisions and collateral estoppel. Dkt. # 50 at 12-16. Apparently, in the Secretary's view, decisions that are "precedential" and those giving rise to "collateral estoppel" are synonymous. This reflects a fundamental misunderstanding of the distinct legal concepts at issue. A "precedential" decision is binding on all lower courts/decision makers, regardless of the parties before the lower court/decision maker. *See, e.g., Allegheny General Hospital v. National Labor Relations Board*, 608 F.2d 965, 969-70 (3rd Cir. 1979). By contrast, "collateral estoppel" focuses on the issues and parties to an earlier litigation and binds those parties in a subsequent litigation of the same issues regardless of the level of review, if any. Recognizing the difference between a decision having "precedential effect" and a decision giving rise to collateral estoppel, prior to the adoption of Fed. R. App. P. 32.1(a) in 2006, numerous federal appellate courts enacted local rules that precluded citation to non-precedential decisions except when cited, *inter alia*, for purposes of collateral estoppel. *See, e.g., 7th Cir. Rule 32.1(b)/(d)* ("Every order

bears the legend: ‘Nonprecedential disposition.’”); (“No order of this court issued before January 1, 2007, may be cited except to support a claim of preclusion (res judicata or collateral estoppel) or to establish the law of the case from an earlier appeal in the same proceeding.”). Simply put, “precedence” and “collateral estoppel” are distinct legal concepts and “precedence” has no bearing on this case.

7. Collateral Estoppel Would Not Interfere With Discretion

On pages 17-24 of the Secretary’s cross motion, the Secretary presents a broad argument that his actions are immune from the opinions of the Supreme Court (*Astoria* and *Utah Construction*) or any legal principles because that would interfere with the Secretary’s “discretion” to implement the Medicare Act. Indeed, the Secretary offers that he has discretion “not to be bound by ALJ rulings.” Dkt. # 50 at 19. In support of this position, the Secretary cites a mishmash of cases, involving disparate facts and irrelevant issues, and quotes various passages from such cases out of context.

Pursuant to *Astoria* and *Utah Construction*, collateral estoppel only applies when a department/agency is acting in a “judicial capacity.” Thus, the Secretary’s citations to, and quotes from, *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030 (D.C. Cir. 2008) and *Comcast Corp. v. F.C.C.*, 526 F.3d 763 (D.C. Cir. 2008), are not relevant because they involve only non-judicial proceedings/statements by

agencies. *See Devon*, 551 F.2d at 1040 (Royalty Policy Board statements); *Comcast*, 526 F.2d at 769 (FCC Media Bureau waivers).

Along these same lines, the Secretary cites and quotes from cases concerning the Provider Reimbursement Review Board (PRRB).⁴ The PRRB is not composed of ALJs. Instead, the PRRB is a five-member panel of “persons knowledgeable in the field of healthcare reimbursement” (42 C.F.R. § 405.1817) charged with reviewing accounting decisions of contractors regarding reimbursements to providers. In the words of the Seventh Circuit, the PRRB is comprised of “minions” within the Department. *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987). Thus, again, the PRRB is not an instance of the Department acting in a “judicial capacity” and its caselaw is irrelevant.

As to the Secretary’s allegation that applying collateral estoppel would interfere with his discretion to decide matters by promulgating rules or by individual adjudication (Dkt. # 50 at 18-19), there is nothing to that. Where the Secretary has elected to proceed by individual adjudication, applying collateral estoppel would not

⁴ *Community Care Foundation v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (non-final decision of PRRB, “a five-member panel of experts”); *Abraham Lincoln Memorial Hospital v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012).

interfere with that choice. Instead, it would only mean that collateral estoppel may, or may not, apply as to that particular plaintiff in that individual adjudication.⁵

For example, the next time that Mrs. Piekanski submits a claim for coverage of her TTFT device, that matter will be individually adjudicated. Based on her earlier favorable decisions, Mrs. Piekanski will assert that (absent changed circumstances) the Secretary is collaterally estopped from denying that TTFT is a covered Medicare benefit for her/is “medically reasonable and necessary.” Indeed, absent changed circumstances, that will be the case in all future claims by Mrs. Piekanski.

The Secretary’s citation to *Int’l Rehab Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (Def. Cross-Mot. Summ. J., Dkt. # 50 at 22) is inapposite because that case involved only an “arbitrary and capricious” review across multiple cases and not collateral estoppel. Likewise, inapposite is the Secretary’s out of context citation to, and quotation from, *Freeman v. U.S. Dep’t of Interior*, 37 F.Supp.3d 313, 344-45 (D.D.C. 2014). *Id.* at 22. The court’s comments that the Secretary references from that decision were in the context of a plaintiff that argued that prior ALJ decisions to which it was not a party “bound” the Department in a

⁵ The Secretary’s reliance on a Departmental Appeals Board decision on safety violations against a long-term care facility is not on point as it does not address collateral estoppel based on prior decisions for the same plaintiff for the same service. *See Avalon Place Trinity*, DAB No. 2819 (2017).

non-mutual, collateral estoppel sense. Citing *Mendoza*, the court there properly rejected that assertion. *Freeman*, F. Supp. 3d. at 346 (“Under these circumstances, the general rule amply applies and no non-mutual preclusive effect is warranted for the ALJ rulings in *Aloisi* and *Story*.”). As already shown, such reasoning is inapplicable where mutuality exists.

The Secretary’s discussion of *Almy* is likewise inapposite. Dkt. # 50 at 21. As indicated above, *Almy* concerned only an “arbitrary and capricious” review across multiple cases (and apparently different plaintiffs) by a plaintiff seeking coverage for “future claims.” Thus, the comments there were in the context of those issues and not collateral estoppel. *See e.g., Almy*, 679 at 310 (discussing how the Medicare Appeals Council is not bound by “decisions of lower reviewing bodies addressing different disputes between different parties”). *Almy*, however, is simply distinguished from the immediate case. Mrs. Piekanski seeks to collaterally estop the Secretary (the same party she prevailed against numerous times in final ALJ decisions) from denying claims for Mrs. Piekanski (the same party who prevailed numerous times in final ALJ decisions) based on the reasonableness and medical necessity of the same device.

Collateral estoppel does not interfere with the Secretary’s discretion to implement the Medicare Act by individual adjudication.

8. The Secretary's Lack of Incentive Argument

The Secretary invokes in his discussion of the unfairness of applying collateral estoppel the “lack of incentive to litigate” exception to collateral estoppel derived from *Parklane*. Dkt. # 50 at 27. Though the reference is limited to a quote, Mrs. Piekanski will address the argument in an abundance of caution. As explained by the Supreme Court in *B & B Hardware, Inc. v. Hargis Indust., Inc.*, 575 U.S. 138 (2015), collateral estoppel may be “inapt if the amount in controversy in the first action was so small in relation to the amount in controversy in the second that preclusion would be plainly unfair.” *Id.* at 159. Likewise, in *Parklane*, the Supreme Court indicated that if the amount in the first action is so small, a party may have little incentive to litigate “particularly if future suits are not foreseeable.” *Parklane*, 439 U.S. at 330. While referencing the exception, the Secretary never makes any effort to demonstrate how it applies here.

First, there is no material disparity between the amounts at stake in both the decisions forming the basis for collateral estoppel and the decision being appealed. Indeed, the stakes are identical in that all of the decisions concern particular months of coverage for the same device. Thus, the Secretary had the same incentive to litigate before ALJs Gulin, Glaze, Soulikias, and Myles as he did before ALJ Glaze.

Second, given that the TTFT device is rented on a monthly basis and that claims will be submitted as long as Mrs. Piekanski is using the device, clearly, future

claims/suits are foreseeable. To the extent that the Secretary's point is that he just did not care about the earlier cases because he did not consider them significant, that demonstrates that the application of collateral estoppel is fair. Because they concern identical issues, each claim by Mrs. Piekanski is just as important as the others. If the Secretary did not care about the earlier cases, then there is no reason not to apply collateral estoppel to the present case because the Secretary still does not care. The Secretary had every incentive to litigate and the application of collateral estoppel would not be unfair. Mrs. Piekanski's motion should be granted.

F. The Secretary's Motion Should Be Denied

To the extent that the Secretary's motion is simply a request that Mrs. Piekanski's motion be denied, that is without basis as detailed above. Regarding the Secretary's assertion that all other grounds challenging ALJ Glaze's decision have been abandoned (Dkt. # 50 at 3, fn. 2), there is no merit to that proposition and it should be rejected. *See* FED.R.CIV.P. 56(a) ("A party may move for summary judgment, identifying each claim or defense – or *the part of each claim or defense* – on which summary judgement is sought.") (emphasis supplied).

IV. CONCLUSION

The triple purposes of collateral estoppel would be served by its application in this case. First, Mrs. Piekanski has already been the subject of multiple ALJ decisions and has had to bear the costs, delays, and uncertainties of that repeated

litigation. Second, if collateral estoppel is not applied, Mrs. Piekanski alone could be the source of as many as four (4) cases on this Court's docket each year.⁶ Third, the application of collateral estoppel would prevent inconsistent results, as demonstrated in this case (e.g., September – November 2017 are covered, December 2017 – February 2018 are not covered, June – August 2018 are covered).

For the reasons set forth above, Mrs. Piekanski's motion should be granted and the Secretary's cross motion for summary judgment should be denied. The Court should hold that the Secretary is collaterally estopped from denying that TTFT is medically reasonable and necessary and a Medicare covered benefit for Mrs. Piekanski, reverse the unfavorable decision of ALJ Glaze, and remand this case with instruction to order coverage of the claims at issue. The Secretary's motion should be denied.

Respectfully submitted,

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⁶ Because claims for coverage are typically submitted every three months.

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Dated: September 18, 2020

CERTIFICATE OF SERVICE

I, Mark W. Fidanza, certify that a true and correct copy of the foregoing Memorandum of Law in Support of Plaintiff's Combined Opposition to Defendant's Cross Motion for Summary Judgment and Reply to Defendant's Opposition to Plaintiff's Motion for Summary Judgment was filed electronically on September 18, 2020, is available for viewing and downloading from the federal court's ECF/CM system, and will be automatically served upon registered counsel of record by ECF/CM.

/s/ Mark Fidanza
Mark Fidanza